K132889/
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Nucletron

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FEB 2 6 2014

Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(k) Summary

September 13, 2013

Submitter of 510(k):

Company name:	Nucletron BV
Registration number:	611894
Address:	Waardgelder 1, 3905 TH Veenendaal, The Netherlands
Phone:	+31 318 557 133
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Correspondent:	Rudolf Vos

New Device Name:

Trade/Proprietary Name:	Fletcher CT/MR Shielded Applicator Set
Common/Usual Name:	Intracavitary Remote Afterloading Applicator
Classification Name:	system, applicator, radionuclide, remote-controlled
Classification:	21 CFR 892.5700, Class II

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Fletcher Williamson Applicator Set	K983341

Description:

The Fletcher CT/MR Shielded Applicator Set is a modification of the Fletcher Williamson Applicator Set (K983341). It is a gynecological applicator for brachytherapy procedures. The applicator uses one intrauterine tube and two ovoid tubes for treatment of the cervix and endometrium cancer. The tubes guide the radioactive source of the afterloader to the location where treatment is to be applied.

Tungsten alloy shielding is incorporated in the ovoid to lower the dose in organs like rectum and bladder during treatment. The shielding position in the ovoid is adjustable, enabling CT imaging with few artifacts. For MR data acquisition and X-ray it is not necessary to move the shields.

The Fletcher CT/MR Shielded Applicator Set is available in two variations and is compatible with Nucletron afterloaders and accessories.

Intended use:
The Fletcher CT/MR Shielded Applicator Set is intended for gynecological brachytherapy treatment of the cervix and endometrium.

Summary of technological considerations:
The operating principle is the same as the marketed device. The modified design combines the characteristics of the marketed device (shielding in the ovoids) with materials that allow CT and MR imaging, enabling 3D treatment planning. The shielding position in the ovoid is adjustable, enabling CT imaging with few artifacts. For MR data acquisition and X-ray it is not necessary to move the shields. Ovoid and intrauterine dimensions of the modified device are comparable to the marketed devices.

Summary of testing:
Validation of sterilization processes and biological evaluation was performed. The device was tested for use in the MR and CT environment. Bench testing (similar to bench testing done to the Legally Marketed Device) shows that the device meets its performance requirements, and that the modified device performance is equivalent to the marketed devices.

Conclusion:
Nucletron considers the Fletcher CT/MR Shielded Applicator Set to be substantially equivalent to legally marketed predicate devices through the data and information presented. No safety or effectiveness issues were identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

February 26, 2014

Nucletron B.V.
% Mr. Rudolf Vos
QA/RA Engineer
Waardgelder 1
Veenendaal, 3905 TH
THE NETHERLANDS

Re: K132889
Trade/Device Name: Fletcher CT/MR Shielded Applicator Set (6 mm/4 mm)
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: II
Product Code: JAQ
Dated: January 30, 2014
Received: February 3, 2014

Dear Mr. Vos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132889

Device Name: Fletcher CT/MR Shielded Applicator Set

Indications for Use: The Fletcher CT/MR Shielded Applicator Set is intended for gynecological brachytherapy treatment of the cervix and endometrium.

Prescription Use X (Part 21 CFR 801 subpart D) AND/OR Over-The-Counter Use_____ (Part 21 CFR 801 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K132889